K043357

MAR 4 - 2005

LINDE MEDICAL SENSORS AG

510(k) Summary

Submitted by:	Linde Medical Sensors AG Austrasse 25 4051 Basel - Switzerland Phone: 011 41 61 278 82 07 Fax: 011 41 61 278 81 81
Contact:	Jean-Pierre Palma Head of Mechanical Engineering / Regulatory Affairs
Date Summary prepared:	October 20, 2004
Trade Name:	TOSCA 500 PCO_2, SpO_2 and Pulse Rate Monitoring System
Common Name:	Cutaneous Gas Monitor / Pulse Oximeter
Classification Name:	Monitor Carbon Dioxide Cutaneous (73LKD) / Oximeter (74DQA)
Substantially Equivalent Device:	Tosca PCO_2, SpO_2 and Pulse Rate Monitoring System 510(k) Number: K032291

Description of the TOSCA 500 PCO_2, SpO_2 and Pulse Rate Monitoring System

The Linde TOSCA 500 Monitoring System is designed for the simultaneous continous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and pulse rate, using a single sensor (Tosca Sensor) applied to the ear lobe.

The system consists of a Tosca Monitor equipped with an integrated calibration unit which allows a fully automatic calibration of the PCO_2 part of the sensor and also provides a storage facility for the sensor, and with the Masimo SET signal extraction technology for the calculation of the functional oxygen saturation and the pulse rate ; a Tosca Sensor comprising the elements of an electrochemical Stow-Severinghaus-type carbon dioxide sensor and of an optical pulse oximetry sensor; supplies for the sensor preparation; supplies for the sensor attachment at the ear lobe; and a gas mixture for the sensor calibration.

Intended Use

The Linde TOSCA 500 Monitoring System is designed for the simultaneous continuous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and pulse rate in adults and pediatrics.

Principles of Operation

The Linde Tosca is used for the simultaneous continuous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and pulse rate, using a single sensor (Tosca Sensor) applied to the ear lobe.

Transcutaneous measurement of PCO_2 makes use of the fact that carbon dioxide gas is able to diffuse through body tissue and skin and can be detected by a sensor at the skin surface. By warming up the sensor, a local hyperemia is induced, which increases the supply of arterial blood to the dermal capillary bed below the sensor.The PCO_2 part of the Tosca sensor consists of a Stow-Severinghaus type electrode. PCO_2 is measured by determining the pH of an electrolyte solution. A change in pH is proportional to the logarithm of the PCO_2 change. The pH is determined by measuring the potential between a miniaturized glass pH electrode and an Ag/AgCl reference electrode. The electrolyte is provided within a thin hydrophilic spacer, which is placed over the sensor surface and is coupled to the skin via a highly gas permeable hydrophobic membrane. The sensor is calibrated in a gas of a known CO_2 concentration. The slope (change of potential with PCO_2) is preset in the sensor memory.

The principle of the SpO_2 measurement is based on the difference in the light absorption characteristics of haemoglobin in its oxygenated and reduced forms. The SpO_2 part of the TOSCA sensor consists of two light emitting diodes, a red (660 nm) and an infrared (880 nm), and a photodiode. The light originating from the diodes passes through the ear lobe and is redirected at the opposite side by a light reflecting material. The light received by the photo detector is converted to electrical signals which are analyzed by the monitor. The signals containing pulsatile components which are caused by variations in blood volume synchronous with cardiac action reflecting inflowing arterial blood and fluctuating absorbance of venous blood due to patient motion are analysed with the Masimo SET Signal Extraction Technology incorporated in the TOSCA 500 Monitor. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by the blood is related to hemoglobin oxygen saturation. The Masimo SET signal processing decomposes the red and infrared pulsatile absorbance signals into an arterial signal plus a noise component and calculates the ratio of the arterial signals without noise. The ratio of the two arterial pulse added absorbance signals and its value is used to find the SpO_2 saturation in an empirically derived equation in the Masimo Set software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia states.

Environmental Testing

Applicable environmental, electrical, EMC and mechanical Testing per Reviewers Guidance for Premarket Submissions – November 1993 were performed and the TOSCA 500 Monitoring System passed all tests.

Biocompatibility Testing

All patient contact materials were tested as Surface Devices with skin contact for prolonged contact duration (24 hours to 30 days) as defined in ISO-10993-1:1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests. All patient contacting material passed.

Non clinical tests performed that support a determination of substantial equivalence

The TOSCA 500 Monitoring System was subjected to bench testing that determined the transcutaneous PCO_2 performances according to IEC 60601-2-23 and IEC 60601-3-1.

The TOSCA 500 Monitoring System was subjected to bench testing using a simulator that determined the saturation and pulse rate performance accuracies under the ranges specified.

Clinical tests performed that support a determination of substantial equivalence

Clinical comparative studies between transcutaneous PCO_2 and arterial blood gas values, using the TOSCA Monitoring System were performed on adults and infants. The results show that the TOSCA System performs as intended and that a good correlation exists between trancutaneous PCO_2 and arterial blood gas values.

Clinical studies using the TOSCA Monitoring System were performed on healthy adults volunteers subjected to induced hypoxia measuring the arterial hemoglobin saturation values and comparing these values to the values determined from arterial blood samplings with a co-oximeter. The results show that the TOSCA System performs as intended and that the specified saturation accuracy is met.

Conclusion

The results of the environmental, bench and clinical testing demonstrate that the TOSCA 500 PCO_2, SpO_2 and Pulse Rate Monitoring System and accessories are safe, effective and performs as well as the predicated device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAR 4 - 2005

Mr. Jean-Pierre Palma
Head of Mechanical Engineering/Regulatory Affairs
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Austrasse 25
Basel, 4051
SWITZERLAND

Re: K043357
Trade/Device Name: TOSCA 500 PCO_2, SpO_2 and Pulse Rate Monitoring System
Regulation Number: 870.2710
Regulation Name: Ear Oximeter
Regulatory Class: II
Product Code: DPZ, LKD
Dated: February 4, 2005
Received: February 7, 2005

Dear Mr. Palma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **TOSCA 500 PCO_2, SpO_2 and Pulse Rate Monitoring System**

Indications For Use:

The Linde TOSCA 500 Monitoring System is designed for the simultaneous continuous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and Pulse Rate in adults and pediatrics.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular, Respiratory, and Neurological Devices
(ODE)

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